

Comments on VAERS-2 form

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Vaccine Adverse Event Reporting System
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Upon reviewing the proposed VAERS-2 form, I have the following comments:

- In general, the form appears more crowded, with smaller print font. I am afraid that the completion of the new form will appear to be more daunting, and this may result in patients and health care providers being more reluctant to file a VAERS report, or to fill in all needed information.
- In Box A- (?)8, specifying age at vaccination, will reduce much confusion.
- In Box B-2, "Responsible Physician" needs to be better defined. For example, if a vaccine is given at a shopping mall or workplace the physician responsible for administering the vaccine often is not known. A suspected AE may likely be brought to the attention of a local practitioner, who would be more likely to provide treatment and report the AE. This person would be considered by many to be the "responsible physician".
- In Box B-1, "County where vaccine is administered", needs to be expanded to areas outside of the US, where many FDA-licensed vaccines are administered, particularly in the military.
- In Box C-8, Physician should be added.
- In Box C, consider a space for reporter e-mail address, which may facilitate follow-up.
- In Box D, Date and Time of vaccination need to be made more prominent to emphasize the critical importance of this information. Do not include separate time entry areas for AM v. PM times.
- Box D, since most existing electronic databases are programmed for the entry of "no. of Previous Doses", and since most health care providers are accustomed to enter the information in this manner, I do not see a reason to make a change to "dose # in Series".
- Box E, the time of "adverse event onset" should not be removed. The onset of AEs is often within minutes of the injection, and this is not well captured in the revised form.

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- Box E-6, the phrase “recovered to his/her *original state of health*” is confusing. This may be impacted by illnesses or events that have nothing to do with the immunization. We are most interested if the patient has recovered from the suspected AE.
- Please explain the value of including “not yet”. From a regulatory standpoint, what should be done with this information?
- Box E- (?)7, The term “required medical intervention to prevent any of the above outcomes” will need significant explanation, particularly for non-health care providers.

All in all, the VAERS-2 form does have some improvements in clarification, however I question whether the amount of additional useful information will outweigh the confusion of transitioning to a new, more crowded format, which may discourage some reporting. Changing and revalidating existing AE databases to accommodate these limited changes will be required. The new form also does not address the issue of multiple suspected adverse events from a single immunization, with different onset times and degrees of seriousness and recovery status.